COVID-19 vaccine risk perception in cancer patients: Psychometric validation of a new screening tool

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♟ *ABSTRACT*. Obiettivo del presente studio-pilota è quello di validare un nuovo strumento di screening per valutare la percezione del rischio e la tendenza ad esitare nei confronti dei vaccini anti-COVID-19 nei pazienti oncologici. Abbiamo reclutato pazienti (n = 356) che fossero in trattamento o in follow-up. Tutti i partecipanti hanno completato diverse misure di percezione del rischio, fiducia nelle istituzioni, aderenza al trattamento e distress psicosociale. Lo scree plot e la parallel analysis suggeriscono una struttura unifattoriale (varianza spiegata = 47.816%). La scala risulta essere uno strumento affidabile costituito da 7 item (α di Cronbach = .806; Ω di McDonald's = .810). Correlazioni e confronti con altre misure hanno confermato la validità concorrente e predittiva. La nuova misura riporta una moderata correlazione (r = .410; p<.001) con la non-aderenza al trattamento, mentre la correlazione con il distress non è significativa. In conclusione, il nuovo questionario sembra essere uno strumento affidabile e valido per valutare la percezione del rischio e la fiducia nei reparti oncologici relativamente alla vaccinazione in pazienti oncologici. Sono necessarie ulteriori ricerche per confermarne la struttura unifattoriale e per comprendere meglio i meccanismi psicologici alla base della reticenza nei confronti della vaccinazione.

♟ *SUMMARY. This study aimed at pilot-testing a new screening tool for assessing risk perception of and hesitancy about anti-COVID-19 in patients diagnosed with cancer. We recruited consecutive cancer patients (n = 356) who were either in treatment or follow-up. All the participants completed several measures of risk perception, confidence in safeguards, treatment adherence, and psychosocial distress. Scree plot and parallel analysis suggest a unifactorial structure (explained variance = 47.816%). The total scale was found a reliable 7-item measure (Cronbach's α = .806; McDonald's Ω= .810). Correlations and comparisons to other measures confirmed concurrent and predictive validity. The new measure reports a moderate correlation (r = .410; p<.001) with treatment non-adherence, whereas the correlation with distress was not significant. In conclusion, the new measure seems to be a reliable and valid tool for assessing risk anti-COVID-19 vaccine hesitancy in patients diagnosed with cancer. Further research is needed to confirm the unifactorial structure or better understand the underlying psychological mechanisms of vaccine hesitancy.*

Keywords: *Cancer, Confidence in safeguards, COVID-19, Health beliefs, Risk perception, Vaccination*

INTRODUCTION

The COVID-19 pandemic has dramatically impacted the national healthcare systems (Rafiq, Batool & Bazaz, 2020) and psychosocial wellbeing (Xiong et al., 2020). Patients diagnosed with cancer are at greater risk for both being more vulnerable to severe forms of COVID-19 (Dai et al., 2020) and being more affected by disruption and delays in cancer care services (Richards, Anderson, Carter, Ebert & Mossialos, 2020).

The perception of anti-COVID-19 vaccination represents one of the biggest challenges of healthcare generally speaking (Fathalla Aboelsaad et al., 2021), and more specifically with regard to cancer patients (Fanciullino, Ciccolini & Milano, 2021): low vaccination rates are reported to increase the risk of infection and serious outcomes, especially in vulnerable individuals. On the one hand, studies on general population report a recurrent anti-COVID-19 hesitancy higher in those with younger age, lower income and education (Byrne et al., 2021). Moreover, general negative attitudes and negative beliefs about healthcare systems were found to be related to the reluctance to and perception of risk about vaccination. On the other hand, little is known about perception risk and confidence in safeguards in cancer patients and their relation to attitudes towards vaccination. The only two available studies report contrasting results: a Polish online survey highlights a positive attitude towards among cancer patients (Brodziak et al., 2021), whereas a Mexican one a recurrent hesitancy (Villarreal-Garza et al., 2021). These divergent outcomes may be due both to cultural differences and to a limited reliability of the measures used. Indeed, both studies did not use standardized measures and relied on online surveys with recruitment via social media.

The current study aimed at developing a standardized measure for assessing risk perception of and hesitancy about vaccination in cancer patients. The new measure was validated psychometrically through consolidated procedures found in the literature (Chan, 2014): (i) a Delphi method was used to create a pool of items through focus groups; (ii) the selected items were then tested in a small group of patients diagnosed with cancer; (iii) after a final review the questionnaire was preliminarily tested in a statistically significant sample of patients (see Procedures and statistical analysis). Specifically, the study aimed at developing a quick screening tool for hospital settings, pilot-testing it directly on cancer patients who were participating in the vaccination campaign within an oncology department. In Appendix we report the psychometrically validated Italian version of the new questionnaire and a translated English version.

MATERIALS AND METHODS

Sample

Three-hundred-fifty-six consecutive cancer patients were recruited from the Department of Oncology, USL Toscana Centro (broad metropolitan area of Florence with over 1.5 million inhabitants) during the vaccination campaign. Inclusion criteria were to be 18 years of age or older, have received a cancer diagnosis, be in treatment or in follow-up, and being able to read and sign the informed consent form in Italian.

The mean age was 63.17 (SD = 11.93) and 65.4% were female (see Table 1). Most respondents had received a new diagnosis (72.8%) and were under treatment (70.2%). Regarding the type of tumor, the majority were patients diagnosed with breast cancer (40.7%).

Measures

- *Coronavirus Risk Perception (CRP)*. CRP is an 8-item measure on a 5-point Likert-type scale assessing the perceive risk perception during COVID-19 (Kanovsky & Halamová, 2020). The scale included items such as "There is a chance, no matter how small I could get the Coronavirus" and the internal reliability of the scale (Cronbach's alpha) in the current study was .787.
- *Confidence in Coronavirus Safeguards* (CCS). CCS is a 10-item measure (on a 5-point Likert-type scale) assessing the confidence in the country safeguards during COVID-19 (Kanovsky & Halamová, 2020). The scale is comprised of items such as "Shops, pharmacies, and drugstores are prepared for Coronavirus"; "My fellow workers behave with adequate caution in regard to the spread of Coronavirus", and the internal reliability of the scale (Cronbach's alpha) in the current study was .813.
- *Depression, Anxiety, Stress Scale (DASS-21)*. It is a measure aimed at assessing symptomatology through 3 single scales and a total score (Henry & Crawford, 2005). The questionnaire comprises 21 items, each on a 4-point

Table 1 – Descriptives of the sample

Age years (*Mean ± SD*)	63.17 ± 11.93
Education years completed (*Mean ± SD*)	11.86 ± 4.64
Sex n (%)	
Male	123 (34.6%)
Female	233 (65.4%)
Relationship status n (%)	
Single	23 (6.5%)
Married	244 (68.5%)
Cohabitating	32 (9%)
Divorced	18 (5.1%)
Widowed	38 (10.7%)
Housing condition n (%)	
Living with my partner/husband/wife	206 (57.9%)
Living by myself	46 (12.9%)
Living with one or more roommates	1 (.3%)
Living with my family	95 (26.7%)
Other	8 (2.2%)
Job condition n (%)	
Full time	100 (28.1%)
Part time	43 (12.1%)
Casual	3 (.8%)
Stood down	1 (.3%)
Unemployed	10 (2.8%)
Not working by choice	23 (6.5%)
Student	2 (.6%)
Retired	169 (47.5%)
Job condition before COVID-19 n (%)	
Full time	136 (38.2%)
Part time	33 (9.3%)
Casual	3 (.8%)
Stood down	–
Unemployed	9 (2.5%)
Not working by choice	18 (5.1%)
Student	1 (.3%)
Retired	151 (42.4%)

Cancer diagnosis n (%)	
New diagnosis	259 (72.8%)
Recurrence	84 (23.6%)
Cancer type n (%)	
Breast	145 (40.7%)
Stomach/bowel cancer	30 (8.4%)
Lung	22 (6.2%)
Gynecological cancer	26 (7.3%)
Prostate cancer	32 (9%)
Testicle cancer	3 (.8%)
Hematological cancer (leukemia. lymphoma)	17 (4.8%)
Other	79 (22.2%)
Current treatment n (%)	
In treatment	250 (70.2%)
Follow up	91 (25.6%)
Treatment type n (%)	
Chemotherapy	109 (30.6%)
Immune therapy	50 (14%)
Hormone therapy	67 (18.8%)
Radiation therapy	20 (5.6%)
Other	23 (6.5%)
PCRS (*Mean ± SD*)	21.79 ± 6.18
CCSS (*Mean ± SD*)	35.63 ± 6.25
CTA (*Mean ± SD*)	17.12 ± 6.27
DASS-21 (*Mean ± SD*)	9.77 ± 10.68
DASS-21 Depression subscale (*Mean ± SD*)	6.97 ± 7.18
DASS-21 Anxiety subscale (*Mean ± SD*)	7.76 ± 8.13
DASS-21 Stress subscale (*Mean ± SD*)	9.77 ± 10.68

Legenda. PCRS = Perceived Coronavirus Risk Scale; CCSS = Confidence in Coronavirus Safeguard Scale; CTA = Cancer Treatment Adherence during COVID-19; DASS-21 = Depression Anxiety Stress Scale.

Likert-type scale. The internal reliability of the scale (Cronbach's alpha) in the current study was .951.

— *Cancer Treatment Adherence during COVID-19 (CTAC).* CTAC is a newly developed measure by first author and colleagues to assess adherence in cancer patients during the pandemic though a single total score (Author et al., 2021). It includes 8 items on a 5-point Likert-type scale and has been linguistically and psychometrically validated in seven languages (Italian, Spanish, Turkish, German-Germany, German-Austria, Chinese, and Swedish). The internal reliability of the scale (Cronbach's alpha) in the current study was .713.

Procedure and statistical analysis

The aim of the study was to psychometrically validate a new screening tool for assessing risk perception and confidence in cancer units about anti-COVID-19 vaccination in cancer patients in hospital settings, namely COVID-19 vaccine risk perception in cancer patients (CVRC). All the recruited patients signed an informed consent form, and the study was approved by the institutional review board of the first author. The questionnaire was created through the following standard procedure (Chan, 2014): (i) we conducted a focus group ($n = 6$) with cancer patients and a focus group ($n = 6$) with multidisciplinary experts (i.e. psycho-oncologists, medical oncologists, cancer nurses) in cancer care; (ii) a first version of the CRVC was then created by all the authors; (iii) another focus group of cancer patients ($n = 8$) preliminary tested the content validity and understandability of the first version. The seven selected items referred to both confidence in cancer unit during vaccination campaign (see Appendix: items 1, 2, 6, and 7) and beliefs about vaccine (see Appendix: items 3, 4, and 5), with higher score indicating higher risk perception about being vaccinated. An English version of the questionnaire has been created (through forward and backward translations) and is included together with the original Italian one in the Appendix.

Finally, CVRC was tested in the study sample ($n = 356$). First, the single items were examined to verify that their distribution was similar to a Gaussian. For items with non-normal distribution, an increasing monotonic transformation (Fox, 2008) of the data was applied.

Second, reliability was calculated through Cronbach's

alpha, and an exploratory Principal Components Analysis (PCA) tested the factorial structure of the new questionnaire (Jolliffe & Cadima, 2016). The factorial structure was confirmed through scree plot and parallel analysis (Patil, Surendra, Sanjay & Donavan, 2017), whereas the reliability of a total score through McDonald's Omega (Hayes & Coutts, 2020).

Finally, content and concurrent validity were examined by calculating correlations (Pearson's r) between CVRC and CRP, CCS, and CTAC. Patients who did not complete all items were excluded from the analyzes ($n = 37$; 12.92% of the total number of patients approached).

RESULTS

The values of kurtosis and skewness (Table 2) show a recurrent right-skewed distribution that is particularly relevant for items 5 and 7. An increasing monotonic transformation of the data was then performed normalizing item 5 (skewness after transformation = 1.298) and 7 (skewness after transformation = 1.414) distribution. All subsequent analyzes were therefore conducted with the normalized scores of items 5 and 7.

CVRC shows a good a reliability through Cronbach's alpha ($\alpha = .806$). As reported in Table 3, the alpha value does not increase if the single items are deleted.

Scree plot and parallel analysis were performed to define the factorial structure (see Figure 1). The scree was only partially significant (leaving room for an even limited possibility of a second factor), while the parallel analysis gave robust results. We estimated mean and percentile eigenvalues (PCA) by assuming a number of random correlation matrices to generate equal to 500 and a percentile of eigenvalues equal to 95. Factor 1 was confirmed by a percentile eigenvalue (1.278479) significantly smaller then the one obtained by PCA (3.301), whereas factor 2 was discharged by a percentile eigenvalue (1.173488) greater than the one obtained by PCA (1.005). Finally, MacDonald's Omega (Hayes & Coutts, 2020) was calculated ($\Omega = .810$), confirming the reliability of a total score as the sum of all the items (CVRC total score; $M = 12.32$; $SD = 5.13$).

Therefore, a PCA (see Table 4) was performed with 1 as fixed number of factors. The obtained factor explained 47.157% of variance (eigenvalue = 3.301). Keiser-Meyer-Olkin measure (KMO = .789) indicated that high proportion

Table 2 – Descriptives of the items of the new measure

	Mean and *SD*	Skewness and Standard Error	Kurtosis and Standard Error
Item 1 - My instinct tells me that the Coronavirus vaccine is probably ineffective.	2.00 (1.23)	1.07 (.12)	.08 (.25)
Item 2 - My instinct tells me that the Coronavirus vaccine is probably dangerous.	1.82 (.95)	1.05 (.12)	.75 (.25)
Item 3 - My cancer unit is not taking the trouble to give me adequate information about the vaccine for Coronavirus.	1.97 (1.19)	1.12 (.13)	.32 (.26)
Item 4 - My cancer unit is not taking the trouble to protect me from the side effects of the vaccine for Coronavirus.	1.91 (1.16)	1.18 (.13)	.49 (.26)
Item 5 - Going to hospital for the vaccination is more of a risk than staying at home and skipping it.	1.55 (1.05)	2.10 (.12)	3.63 (.25)
Item 6 - From the start of the vaccination for Coronavirus. I have avoided finding out how and when to be vaccinated.	1.69 (1.10)	1.66 (.13)	1.86 (.26)
Item 7 - I think that the Coronavirus vaccine is more dangerous than Coronavirus itself.	1.46 (.89)	2.25 (.12)	4.96 (.25)

of the variance of the items might be a result of underlying factors (Kaiser, 1974). Bartlett's Test (Chi-square = 762.942; df = 21; p<.001) (Bartlett, 1937) supported the hypothesis that the correlation matrix is different from identity matrix and may subject to factor analysis. Table 5 presents factor loadings for PCA.

Then, construct and concurrent validity were explored through Pearson's r correlation (see Table 6) between the CRVC total score and measures of confidence in safeguards (CCS), risk perception (CRP), treatment adherence (CTAC), and psychosocial distress (DASS-21).

CVRC total score reported a significant positive correlation with treatment adherence (r = .410; p<.001), a significant positive (even small) correlation with risk perception (r = .168; p<.001), and a significant negative (even small) correlation with confidence in safeguards (r = −.110; p<.001). Focusing on the stronger association, we can suggest that the higher the total score the lower the treatment adherence.

Finally, age, sex, and education did anot report a significant correlation with CRVC total score (p>.05). Neither sex, nor time from diagnosis showed a significant difference at Student's t between males and females (p>.05) and between new diagnosis and recurrence or in-treatment or follow-up (p>.05), respectively. No significant differences were found regarding the type of either treatment or cancer.

Table 3 – Descriptives and reliability of the items of the new measure

Cronbach's α = .806	Mean if item deleted*	Variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Item 1 - My instinct tells me that the Coronavirus vaccine is probably ineffective.	10.33	20.00	.44	.80
Item 2 - My instinct tells me that the Coronavirus vaccine is probably dangerous.	10.53	20.92	.53	.78
Item 3 - My cancer unit is not taking the trouble to give me adequate information about the vaccine for Coronavirus.	10.35	18.72	.59	.77
Item 4 - My cancer unit is not taking the trouble to protect me from the side effects of the vaccine for Coronavirus.	10.41	18.54	.64	.76
Item 5 - Going to hospital for the vaccination is more of a risk than staying at home and skipping it.	10.79	20.35	.54	.78
Item 6 - From the start of the vaccination for Coronavirus. I have avoided finding out how and when to be vaccinated.	10.64	20.36	.49	.79
Item 7 - I think that the Coronavirus vaccine is more dangerous than Coronavirus itself.	10.89	21.15	.57	.77

Note: Total score *Mean* = 12.32; Total score *Standard Deviation* = 5.13.
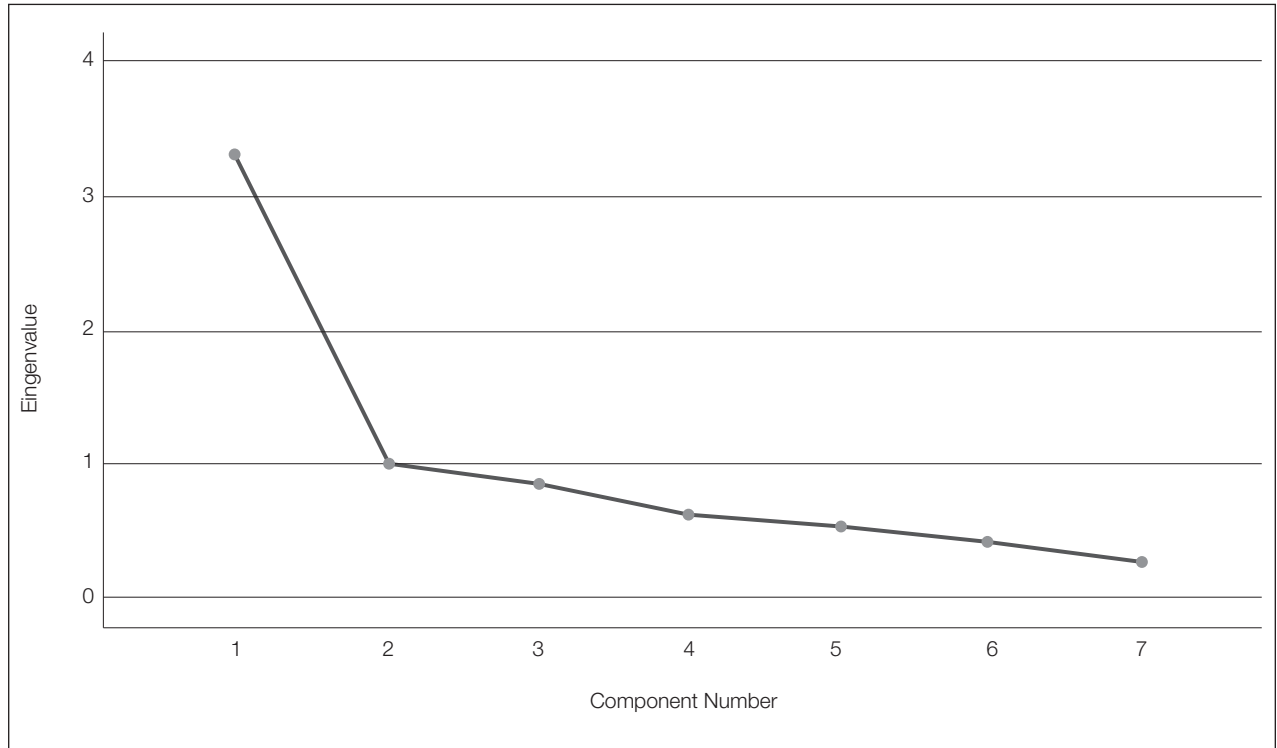
Figure 1 – Scree Plot

Table 4 – Total variance explained

Factor	Eigenvalue	% of variance	Cumulative %
1	3.301	47.157	47.157

Note. Extraction method: Principal Component Analysis (fixed number of factors = 1).

Table 5 – Components matrix

	1
Item 1 - My instinct tells me that the Coronavirus vaccine is probably ineffective.	.587
Item 2 - My instinct tells me that the Coronavirus vaccine is probably dangerous.	.668
Item 3 - My cancer unit is not taking the trouble to give me adequate information about the vaccine for Coronavirus.	.730
Item 4 - My cancer unit is not taking the trouble to protect me from the side effects of the vaccine for Coronavirus.	.760
Item 5 - Going to hospital for the vaccination is more of a risk than staying at home and skipping it.	.687
Item 6 - From the start of the vaccination for Coronavirus. I have avoided finding out how and when to be vaccinated.	.642
Item 7 - I think that the Coronavirus vaccine is more dangerous than Coronavirus itself.	.718

Note. Extraction method: Principal Component Analysis (fixed number of factors = 1)

Table 6 – Intercorrelations among measures

		PCRS	CCSS	CTA	DASS_T
Total score	Pearson correlation	.168**	−.110*	.410**	.022
	Sig. (2-tailed)	.002	.042	.000	.710

Legenda. PCRS = Perceived Coronavirus Risk Scale; CCSS = Confidence in Coronavirus Safeguard Scale; CTA = Cancer Treatment Adherence during COVID-19; DASS_T = total score of Depression Anxiety Stress Scale.

DISCUSSION

Our study aimed at validating a new screening tool for assessing risk perception of and confidence in safeguards about anti-COVID-19 vaccination campaign in patients diagnosed with cancer. To our knowledge this is the first study doing this. Indeed, only two studies with contrasting results and methodological biases (e.g. online anonymous recruitment; non-validated measures) have been published about attitudes about anti-COVID-19 vaccination in those diagnosed with cancer (Brodziak et al., 2021; Villarreal-Garza et al., 2021). Further research is needed to better understand factors that may influence adjustment to COVID-19 therapeutic and preventive strategies in patients at high risk. The resolution of pandemic seemingly happens through a deeper understanding of attitudes and beliefs about vaccines, COVID-19 and healthcare systems (Akarsu et al., 2021; Habas et al., 2020).

Our results suggest that CVRC is a reliable and valid tool for assessing negative attitudes about vaccination in patients diagnosed with cancer. We obtained mixed results in regard to the factorial structure. PCA seemingly suggested a two-factor structure, while parallel analysis strongly supported a unifactorial structure. On the one hand, construct and concurrent validity suggests the reliability of the CVRC total score and so of an unifactorial structure. On the other hand, we previously hypothesized two subscales, consistently with the semantic contents of the items: one about "non-confidence in cancer units" (items 3, 4, and 5), and one about "negative vaccine beliefs" (items 1, 2, 6, and 7). This discrepancy may be due to either a single dimension of vaccine hesitancy regardless of the specific contents of the items, or a small sample size that does not allow to confirm the two-factor structure. What we present here are the results of a pilot-study which will be followed by a confirmatory factor analysis (CFA).

That said, our analysis suggests the validity of a total score. On the one hand, socio-demographic and medical background is seemingly not affecting the results. On the other hand, the only significant and moderate correlation was between vaccine hesitancy and treatment adherence, confirming the concurrent validity of the measure. Those with high hesitancy are at greater risk for reducing adherence.

We hypothesize that there are numerous variables in terms of both specific vaccination attitudes and personality traits that seem not to expose the person to greater or lesser hesitancy. Further research should explore these possible predictors of vaccine hesitancy. In our future confirmatory study (CFA), we aim to extend the variables for concurrent validity.

Importantly, there were two main limitations. First, although our sample size is acceptable, it does allow for the stratification of CVRC score based on the type of diagnosis and treatment. Given the complexity of cancer care, more studies are needed. Second, the total score did not show a correlation with psychosocial distress (DASS-21). Therefore, the present study did not report a predictive validity with respect to psychopathological measures. Future research will need to show whether this is a CVRC limitation or the result of different and not necessarily pathological psychosocial mechanisms (e.g. health beliefs; personality traits).

In conclusion, our pilot-study suggests the validity of the newly developed measure of anti-COVID-19 vaccine hesitancy in cancer patients. Further research should confirm the unifactorial structure and extend its predictive validity.

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APPENDIX

COVID-19 vaccine risk perception in cancer patients – English version

INSTRUCTIONS: Please read each sentence carefully before answering. Use the scale of 5 alternatives shown next to each sentence, choosing the number you consider most appropriate to represent what is true for you.

1 = Completely disagree

2 = Disagree

3 = Don't know

4 = Agree

5 = Completely agree

Item	1 Completely disagree	2 Disagree	3 Don't know	4 Agree	5 Completely agree
1. My instinct tells me that the Coronavirus vaccine is probably ineffective.					
2. My instinct tells me that the Coronavirus vaccine is probably dangerous.					
3. My cancer unit is not taking the trouble to give me adequate information about the vaccine for Coronavirus.					
4. My cancer unit is not taking the trouble to protect me from the side effects of the vaccine for Coronavirus.					
5. Going to hospital for the vaccination is more of a risk than staying at home and skipping it.					
6. From the start of the vaccination for Coronavirus, I have avoided finding out how and when to be vaccinated.					
7. I think that the Coronavirus vaccine is more dangerous than Coronavirus itself.					

Covid-19 vaccine risk perception in cancer patients – Italian version

ISTRUZIONI: La preghiamo di leggere con attenzione ogni frase prima di rispondere. Utilizzi la scala a 5 alternative che è riportata accanto ad ogni frase, scegliendo il numero che ritiene più appropriato nel rappresentare quel che per lei è vero.

1 = Totalmente in disaccordo

2 = In disaccordo

3 = Non so

4 = D'accordo

5 = Totalmente d'accordo

Item	1 Totalmente in disaccordo	2 In disaccordo	3 Non so	4 D'accordo	5 Totalmente d'accordo
1. Il mio istinto mi dice che è probabile che il vaccino per il Coronavirus sia inefficace.					
2. Il mio istinto mi dice che è probabile che il vaccino per il Coronavirus sia pericoloso.					
3. La mia unità oncologica non si preoccupa di informarmi adeguatamente sul vaccino per il Coronavirus.					
4. La mia unità oncologica non si preoccupa di tutelarmi dagli effetti collaterali del vaccino per il Coronavirus.					
5. Andare in ospedale a fare il vaccino è più rischioso che stare a casa e saltarlo					
6. Dall'inizio della vaccinazione per il Coronavirus, ho evitato di informarmi su come e quando essere vaccinato.					
7. Ritengo che il vaccino per il Coronavirus sia più pericoloso del Coronavirus stesso.					